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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
COOK, LISA V	
ART UNIT	PAPER NUMBER
1641	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/09/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/673,077	VALKIRS ET AL.	
	Examiner	Art Unit	
	Lisa V. Cook	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 November 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/7/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicants response to the non-final action mailed 02 August 2006 is acknowledged (Paper filed 11/7/06). In the amendment filed therein the specification, claim 2, claim 10, and claim 24 were modified. Currently claims 1-24 are pending and under consideration.

2. Objections and/or rejections or record not reiterated herein have been withdrawn.

OBJECTIONS MAINTAINED

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-24 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1-24 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

Claims 1-24 are drawn to "markers related to" and "marker related thereto". The written description is not commensurate in scope with the claims drawn to "markers related to" and "marker related thereto". Neither the specification nor the claims teach how to define or obtain "markers related to" and "marker related thereto".

There is no guidance as to what the "markers related to" and "marker related thereto" or how much derivation can occur while retaining the required product characteristics necessary to be considered a "markers related to" and "marker related thereto", reading on the instant claims. There is no guidance as to what the "markers related to" and "marker related thereto" are or which "markers related to" and "marker related thereto" can or cannot be used in the method being claimed. The specification does not include structural examples of "markers related to" and "marker related thereto". Thus, the resulting "markers related to" and "marker related thereto" could result in a complexes not taught and enabled by the specification.

Vas-Cath Inc. V. Mahurkar, 19 USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (*See Vas-Cath* at page 1116).

Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 USC 112 is severable from its enablement provision (see page 115).

The skilled artisan cannot envision the detailed structure of the "markers related to" and "marker related thereto", thus conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. An adequate description requires more than a mere statement that it is part of the invention and a reference to a potential method of isolating it. The court indicated that while Applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a representative number of molecules falling within the scope of the claimed genus.

Therefore the full breadth of the claims, do not meet the written description provision of 35 USC 112, first paragraph.

Response to Arguments

Applicant argues that the instant disclosure provides a clear definition and extensive guidance to the artisan with regard to the claimed "related markers and markers related thereto". Specifically, Applicant directs Examiner to paragraphs [0092]-[0098] of the specification. This argument has been carefully considered but not found persuasive because although the ability to generate BNP fragments via proteolysis as exemplified in the disclosure maybe known to the skilled artisan, the ability to utilize the obtained fragments in a method to characterize a risk of future cerebral vasospasm in a subject suffering from a subarrachnoid hemorrhage is not possessed by the instant specification.

First, the claims are not limited to only the measurement of BNP and its fragments as set forth in the disclosure but to the determination of a plurality of subject-derived markers related to various diseases and or related to the parent marker. The specification does not define or characterize the required relationship between the fragment and parents to thereby retain the same functional capability.

As such "markers related to" parent molecules or a particular disorder are not possessed absent their clear and precise identification and proven capability in the instantly claimed method.

The board has determined that claims lack adequate written description when the specification does not set forth the full scope of either a DNA or protein by way of reference of knowledge in the art of the structure, formula, chemical name, or physical property of the DNA or proteins. See *Capon v. Eshhar,* 418 F.3d 1349 (8/12/05) (Newman, Mayer, Gajarsa). In the instant case, structures of the markers related to the parent or disease are not set forth in the disclosure or in the art to show their presence or amount for the claimed method. In short, the "markers related thereto" have no apparent common link by which they can be determined or identified in a method relating to future risk of cerebral vasospasm in a subject suffering from a subarrachnoid hemorrhage. Further, the markers are taught to be fragments but the epitope(s) of interest with respect to the instantly claimed method is not known. Thus it appears that no common link to identify and establish a proper working structure for the claimed method exists for the marker related thereto.

Secondly, mere plausibility is not the test for rejections under section 112. In particular, Rasmusson v. SmithKline Beecham Corp., 75 USPQ2d 1297 (CA FC 2005) recite "If mere plausibility were the test for enablement under section 112, applicants could obtain patent rights to "inventions" consisting of little more than respectable guesses as to the likelihood of their success. When one of the guesses later proved true, the "inventor" would be rewarded the spoils instead of the party who demonstrated that the method actually worked. That scenario is not consistent with the statutory requirement that the inventor enable an invention rather than merely proposing an unproved hypothesis".

In essence, Applicant is claiming methods of detecting unidentified markers or fragments (markers related thereto) and correlating these unidentified markers or fragments to risk of future cerebral vasospasm in a subject suffering from a subarrachnoid hemorrhage. However, such an immunoassay is not disclosed in the specification (A method measuring unidentified markers or fragments and their correlation to risk of future cerebral vasospasm in a subject suffering from a subarrachnoid hemorrhage). Since the claims encompass the detection of uncharacterized or unknown markers and/or fragments, the examiner maintains for the reasons of record that Applicant does not possess the claimed method invention.

DECLARATION

4. The Declaration under 37 CFR 1.132 filed 11/7/06 by Dr. Kenneth F. Buechler is insufficient to overcome the rejection of claims 1-24 based upon the 112, 1st paragraph rejection as set forth in the last Office action and reiterated above because: the phrases "markers related to" and "markers related thereto" read on unidentified and/or uncharacterized marker fragments that are not possessed by the instant method for detecting vasospasm in SAH patients. Although the declaration contends that the method can utilize antibodies recognizing specific epitopes necessary for assay binding and evaluation, the disclosure does not identify the necessary epitopes necessary for the claimed assay. Accordingly the rejection is maintained.

NEW GROUNDS OF REJECTIONS

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negative by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

I. Claims 1-4 and 19-24 are rejected under 35 U.S.C. 103(a) as being obvious over Jackowski (U.S. Patent #6,235,489) in view of Charpentier et al. (Stroke, 1999, Vol.30, pages 1402-1408).

Jackowski discloses methods for assessing stroke (brain or temporal change) via the measurement of multiple markers. These markers include calbindin-D, myeline basic protein, S-100β, and thrombomodulin. The detection of these markers can distinguish and/or differentiate between ischemic and hemorrhagic events.

Jackowski teaches the determination of a plurality of patient derived markers which are correlated to a subarrachnoid hemorrhage. See abstract, figure 2, and column 3-4, for example.

Jackowski differs from the instant invention in not specifically assessing the future risk of cerebral vasospasm in the subject suffering from subarrachnoid hemorrhage.

However, Charpentier et al. disclose procedures for measuring cerebral vasospasm risk and/or occurrence after aneurismal subarrachnoid hemorrhage. See abstract and page 1403. Charpentier et al. identifies age, WFNS clinical grade, and hyperglycemia as factors that are associated with vasospasm occurrence. Charpentier et al. also disclose that the initial hemorrhage may expose the brain to secondary insults. See page 1407 1st column. Further, the reference teaches that cerebral arterial vasospasm with delayed ischemic neurological deficit occurs in 17% to 40% of patients with aneurismal subarrachnoid hemorrhage. See page 1402.

As a consequence of cerebral vasospasm patients required longer intensive care unit stay and longer hospital stay. See page 1405 2nd column – consequences of cerebral vasospasm.

Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to characterize vasospasm risk as taught by Charpentier et al. in the SAH patients identified in the method of Jackowski (U.S. Patent #6,235,489) because Charpentier et al. taught that cerebral arterial vasospasm with delayed ischemic neurological deficit occurs in 17% to 40% of patients with aneurismal subarrachnoid hemorrhage. See page 1402 and 1403.

One of skill in the art would have been motivated to characterize vasospasm risk in order to reduce patient intensive care stay and increase hospitalization periods. See page 1405 2nd column – consequences of cerebral vasospasm.

II. Claims 1-4 and 19-24 are rejected under 35 U.S.C. 103(a) as being obvious over Jackowski (WO 00/52476) in view of Charpentier et al. (Stroke, 1999, Vol.30, pages 1402-1408).

Jackowski discloses method for assessing stroke (brain or temporal change) via the measurement of multiple markers. These markers include calbindin-D, myeline basic protein, S-100β, and thrombomodulin.

The detection of these markers can distinguish and/or differentiate between ischemic and hemorrhagic events. Jackowski teaches the determination of a plurality of patient derived markers which are correlated to a subarrachnoid hemorrhage. See abstract, figure 2, and column 3-4, for example. See page 2 lines 11-22 and figure 2/6, for example.

Jackowski differs from the instant invention in not specifically assessing the future risk of cerebral vasospasm in the subject suffering from subarrachnoid hemorrhage.

However, Charpentier et al. disclose procedures for measuring cerebral vasospasm risk and/or occurrence after aneurismal subarrachnoid hemorrhage. See abstract and page 1403. Charpentier et al. identifies age, WFNS clinical grade, and hyperglycemia as factors that are associated with vasospasm occurrence. Charpentier et al. also disclose that the initial hemorrhage may expose the brain to secondary insults. See page 1407 1st column. Further, the reference teaches that cerebral arterial vasospasm with delayed ischemic neurological deficit occurs in 17% to 40% of patients with aneurismal subarrachnoid hemorrhage. See page 1402.

As a consequence of cerebral vasospasm patients required longer intensive care unit stay and longer hospital stay. See page 1405 2nd column – consequences of cerebral vasospasm.

Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to characterize vasospasm risk as taught by Charpentier et al. in the SAH patients identified in the method of Jackowski (WO 00/52476) because Charpentier et al. taught that cerebral arterial vasospasm with delayed ischemic neurological deficit occurs in 17% to 40% of patients with aneurismal subarrachnoid hemorrhage. See page 1402 and 1403.

One of skill in the art would have been motivated to characterize vasospasm risk in order to reduce patient intensive care stay and increase hospitalization periods. See page 1405 2nd column – consequences of cerebral vasospasm.

III. Claims 6-8, 15, 17 and 18 are rejected under 35 U.S.C. 103(a) as being obvious over Jackowski (U.S. Patent #6,235,489) or Jackowski (WO 00/52476) in view of Charpentier et al. (Stroke, 1999, Vol.30, pages 1402-1408) and further in view of Yakovlev et al. (The Journal of Neuroscience, October 1, 1997, 17(19), pages 7415-7424).

Please see Jackowski (U.S. Patent #6,235,489) or Jackowski (WO 00/52476) in view of Charpentier et al. (Stroke, 1999, Vol.30, pages 1402-1408) as set forth above.

Jackowski (U.S. Patent #6,235,489) or Jackowski (WO 00/52476) in view of Charpentier et al. (Stroke, 1999, Vol.30, pages 1402-1408) differ from the instant invention in not specifically teaching the detection of the marker caspase-3.

However, Yakovlev et al. disclose methods to determine caspase-3 in temporal profiles of apoptosis after brain injury. See abstract. Caspase-3 levels were elevated in brain injury and the inhibition of caspase-3 markedly attenuated apoptosis induced by TBI in vivo and improved neurological recovery. See page 7422, 2nd column. These results may prove the basis for new therapeutic treatments of CNS injury. See page 7423.

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to evaluate caspase-3 as taught by Yakovlev et al. in the method of Jackowski (U.S. Patent #6,235,489) or Jackowski (WO 00/52476) in view of Charpentier et al. (Stroke, 1999, Vol.30, pages 1402-1408) because Yakovlev et al. taught that caspase-3 levels were elevated in brain injury and the inhibition of caspase-3 markedly attenuated apoptosis induced by TBI in vivo and improved neurological recovery. See page 7422, 2nd column. These results may prove the basis for new therapeutic treatments of CNS injury. See page 7423.

IV. Claim 5 is rejected under 35 U.S.C. 103(a) as being obvious over Jackowski (U.S. Patent #6,235,489) or Jackowski (WO 00/52476) in view of Charpentier et al. (Stroke, 1999, Vol.30, pages 1402-1408) and further in view of Ronn et al. (WO 00/18801).

Please see Jackowski (U.S. Patent #6,235,489) or Jackowski (WO 00/52476) in view of Charpentier et al. (Stroke, 1999, Vol.30, pages 1402-1408) as set forth above.

Jackowski (U.S. Patent #6,235,489) or Jackowski (WO 00/52476) in view of Charpentier et al. (Stroke, 1999, Vol.30, pages 1402-1408) differ from the instant invention in not specifically teaching the detection of NCAM or neural cell adhesion molecule.

However, Ronn et al. disclose methods to determine and assess the NCAM marker. See abstract, page 16 lines 8-31, and page 34 lines 11-28. The marker is useful in the evaluation of several disorders including stroke. Absent evidence to the contrary, it would have been obvious to one of ordinary skill in the art to employ the marker NCAM to assess stroke because the prior art has established the relationship between NCAM and stroke. See WO 00/52476 to Ronn et al.

Accordingly, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use NCAM as a marker for stroke, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

V. Claims 9-11 are rejected under 35 U.S.C. 103(a) as being obvious over Jackowski (U.S. Patent #6,235,489) or Jackowski (WO 00/52476) in view of Charpentier et.al. (Stroke, 1999, Vol.30, pages 1402-1408) and further in view of Greenberg (Drug News and Perspectives, 1998, Vol.11, No.5, pages 265-270. Abstract Only).

Please see Jackowski (U.S. Patent #6,235,489) or Jackowski (WO 00/52476) in view of Charpentier et al. (Stroke, 1999, Vol.30, pages 1402-1408) as set forth above.

Jackowski (U.S. Patent #6,235,489) or Jackowski (WO 00/52476) in view of Charpentier et al. (Stroke, 1999, Vol.30, pages 1402-1408) differ from the instant invention in not specifically teaching the detection of the marker VEGF.

However, Greenberg discloses that stroke results from focal cerebral ischemia due to the occlusion of cerebral blood vessels (angiogenesis). Greenberg further teaches that VEGF is a key mediator of angiogenesis and cerebral ischemia. The understanding of VEGF may have implications for prognosis and treatment in stroke. See abstract.

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to evaluate VEGF as taught by Greenberg in the method of Jackowski (U.S. Patent #6,235,489) or Jackowski (WO 00/52476) in view of Charpentier et al. (Stroke, 1999, Vol.30, pages 1402-1408) because Greenberg taught that that VEGF is a key mediator of angiogenesis and cerebral ischemia. The understanding of VEGF may have implications for prognosis and treatment in stroke. See abstract.

VI. Claims 12-14 and 16 are rejected under 35 U.S.C. 103(a) as being obvious over Jackowski (U.S. Patent #6,235,489) or Jackowski (WO 00/52476) in view of Charpentier et al. (Stroke, 1999, Vol.30, pages 1402-1408) and further in view of Roger et al. (Journal of the American College of Cardiology, 1999, Vol.34, No.1, pages 155-162).

Please see Jackowski (U.S. Patent #6,235,489) or Jackowski (WO 00/52476) in view of Charpentier et al. (Stroke, 1999, Vol.30, pages 1402-1408) as set forth above.

Jackowski (U.S. Patent #6,235,489) or Jackowski (WO 00/52476) in view of Charpentier et al. (Stroke, 1999, Vol.30, pages 1402-1408) differ from the instant invention in not specifically teaching the detection of the detection of a marker relating to blood pressure, such as BNP (B-type natruiuretic peptide) or brain natriuretic peptide.

However, Roger et al. disclose methods measuring BNP and its effects on hemodynamics. BNP is elevated in patients with heart failure, and serves as a sensitive and specific serologic marker for left ventricle dysfunction. BNP is disclosed as a component in the modulation of cardiac and vascular function and fluid status. See page 155. The studies included stroke patients. See Table 1 on page 156. The measurement and monitoring of BNP was found useful in the assessment of the drug nesiritide. See 161.

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to evaluate BNP as taught by Roger et al. in the method of Jackowski (U.S. Patent #6,235,489) or Jackowski (WO 00/52476) in view of Charpentier et al. (Stroke, 1999, Vol.30, pages 1402-1408) because Roger et al. taught that BNP is a component in the modulation of cardiac, vascular function, and fluid status. See page 155. Since stroke and vasospasms are related to blood vessel flow, one of ordinary skill in the art would have evaluated BNP in order to monitor blood flow as it relates to these disorders.

Response to Arguments

Applicant contends that the primary references to Jackowski did not anticipate the instant invention because they were silent with respect to the risk of vasospasm occurrence in SAH patients. This argument was carefully considered and found persuasive. Accordingly the reference to Jackowski have been combined with Charpentier et al. (Stroke, 1999, Vol.30, pages 1402-1408) to make the instant invention obvious.

With respect to the remaining rejections, Applicant argues that they could not remedy the deficiencies of the references to Jackowski. This argument was considered and addressed herein. Specifically, Charpentier et al. (Stroke, 1999, Vol.30, pages 1402-1408) has been added to all the rejections to cure the deficiency of Jackowski.

6. For reasons aforementioned, no claims are allowed.

7. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Group 1641 – Central Fax number is (571) 273-8300, which is able to receive transmissions 24 hours/day, 7 days/week. In the event Applicant would like to fax an unofficial communication, the Examiner should be contacted for the appropriate Right Fax number.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lisa V. Cook whose telephone number is (571) 272-0816. The examiner can normally be reached on Monday - Friday from 7:00 AM - 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, can be reached on (571) 272-0823.

Any inquiry of a general nature or relating to the status of this application should be directed to Group TC 1600 whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

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